SUPPORTING STATEMENT
FOR THE
ORGAN PROCUREMENT ORGANIZATION/HISTOCOMPATIBILITY LABORATORY
STATEMENT OF REIMBURSABLE COST, MANUAL INSTRUCTIONS AND SUPPORTING
REGULATIONS CONTAINED IN 42 CFR 413.20 AND 413.24-FORM CMS -216

## A. BACKGROUND

CMS is requesting reapproval of the Form, CMS-216-94 (OMB No.0938-0102). The current form implements various provisions of the Social Security Act including Section 1881 (a) which provides Medicare coverage for end stage renal disease patients, who meet certain entitlement requirements, and kidney donors. It also implements Sections 1881 (b)(2)(B) and 1861 (v)(1)(A) of the Social Security Act to determine the reasonable costs incurred to furnish treatment for renal patients and transplant patients. OMB approval of the Form CMS-216-94 expires August 31, 2008.

The following is a summary of the cost reporting forms. No revisions are proposed to the worksheets and the major worksheets are listed below in order of their sequence. Further instructions for the completion of the particular worksheets are provided in the attachment-Provider Reimbursement Manual, Part II, Chapter 33.

1. Worksheet S - Organ Procurement Organization/Histocompatibility Laboratory General Data and Certification Statement

2. Worksheet S-1 - Organ Procurement Organization Histocompatibility Laboratory Identification Data

3. Worksheet A - Reclassification and Adjustment of Trial Balance of Expenses

4. Worksheet B- Cost Allocation-General Service Costs

5. Worksheet C & D - Computation of Medicare Cost & Calculation of Reimbursement Settlement

6. Worksheet E- Balance Sheet

## B. Justification

### 1. Need and Legal Basis

Section 1881(b)(2)(B) of the Social Security Act requires each independent Organ

Procurement Organization (OPO) and Histocompatibility Laboratory (HL) to be paid the reasonable costs for its services. According to Section 1861(v)(1)(A), the reasonable cost is the aggregate actual costs incurred minus nonallowable costs for the purpose of Medicare reimbursement. An example of a nonallowable cost for Medicare reimbursement is advertising cost. The reasonable costs of securing and transporting organs cannot be determined for the fiscal year until the OPO/HL files its cost report (Form CMS-216) at year-end and costs are verified by the Medicare fiscal intermediary. During the fiscal year, an interim rate has been set based on cost report data from the previous year. The OPO/HL bills the transplant hospital for services rendered. The transplant hospital pays interim payments, approximating reasonable cost, to the OPO/HL. So that the hospital will not be disadvantaged by having to advance funds for the purchase of services it receives from the OPO/HL, the Medicare fiscal intermediary, Riverbend Government Benefits Administrator, reimburses the hospital an interim reimbursement rate. When the OPO/HL Form CMS-216 is filed by each OPO/HL at the end of its fiscal year, there is a retroactive adjustment so that increases in costs or overpayments are taken fully into account. This retroactive adjustment is the total amount of allowable costs minus the total interim payments, deductibles, and coinsurance amounts receivable from beneficiaries. The difference between the reimbursement due and the payments made is the amount of retroactive adjustment. Therefore, the Form CMS-216, Organ Procurement/Histocompatibility Laboratory Cost Report is a settlement cost report. Also, it provides Medicare with the information necessary to reimburse OPO/HL facilities on a reasonable cost basis.

In addition, 42 CFR 413.20(b) requires that cost reports will be required from providers on an annual basis. Such cost reports are required to be filed with the provider's fiscal intermediary. The fiscal intermediary uses the cost report to make settlement with the provider for the cost reporting period covered by the cost report. Further, the fiscal intermediary uses the cost report to decide whether or not to audit the records of the provider. 42 CFR 413.24(a) requires providers, receiving payment on the basis of reimbursable cost, to provide adequate cost data based on their financial and statistical records which must be capable of verification by qualified auditors.

2. Information Users

Riverbend Government Benefits Administrator is the single intermediary servicing all independent OPOs and HLs participating in Medicare. Using the previous year's cost report for an OPO/HL, Riverbend establishes an interim reimbursement rate based on the average cost per service after making appropriate audit adjustments. During the fiscal year, Riverbend reimburses each hospital the interim reimbursement rate the hospital paid for the pretransplantation services provided by the OPOs or HLs. At the end of the fiscal year, the OPO/HL completes Form CMS-216 and files the cost report form with Riverbend. Then, Riverbend performs an annual year-end cost settlement for each independent OPO and HL facility for services provided. A year end cost report settlement takes place directly between Riverbend and the OPO/HL with retroactive adjustments being made. If the determination of reasonable cost reveals an overpayment, the OPO/HL must pay the overpayment to Riverbend. If the determination of reasonable cost reveals an underpayment, the OPO/HL will be paid the underpayment amount by Riverbend.

3. Improved Information Technology

Currently, there are 108 OPOs and/or HLs using computer software to prepare their annual cost report. For cost reporting periods ending on or after September30, 2005,OPO's are required to submit a cost report via an electronic medium.

4. Duplication and Similar Information

The cost report Form CMS-216 is a one of a kind form that does not duplicate any other information. This form specifically provides for the reimbursement methodology that is unique to OPOs and HLs.

5. Small Business

CMS has modeled this cost report after those of small businesses in order to minimize the public burden.

6. Less Frequent Collection

If the annual cost report is not filed, CMS through its contractor, the fiscal intermediary, will be unable to determine whether proper payments are being made under the Medicare Program. If a cost report is not filed, the intermediary has the authority to reduce or suspend interim payments. In addition, if a provider fails to file a cost report, all interim payments made since the beginning of the cost reporting period may be deemed an overpayment, and recovery action may be initiated.

7. Special Circumstances

This information collection complies with all general information guidelines as described in 5 CFR 1320.6

8. Federal Register Notice/Outside Collection

The 60-day Federal Register notice was published in the Federal Register on February 29, 2008, attached.

Whenever CMS plans to revise CMS Form-216, it sends the initial revised cost report and instructions to all independent OPOs and HLs for comment. We review and incorporate, where applicable, all relevant comments.

9. Payment/Gift to Respondents

There are no payments or gifts to respondents.

10. Confidentiality

CMS does not pledge confidentiality of either the statistical or financial data reported on this form.

11. Sensitive Questions

There are no questions of a sensitive nature included on this form.

12. Estimate of Burden (Hours & Wages)

There are approximately 108 OPOs/HLs certified for the Medicare program. It is estimated that it takes 30 hours for reporting and 15 hours for record keeping for a total of 45 hours to complete the Form CMS-216. Thus, the burden is calculated as 45 hours per response multiplied by 108 facilities totaling 4,860 hours. OPOs and HLs are required to prepare the Form CMS-216 annually, after the close of their cost reporting periods.

The previous OMB submission contained 108 facilities and 4,860 burden hours. No facility has been certified since the previous submission. The current burden is 108 facilities and 4,860 burden hours.

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| Contractor Handling<br>(This is the amount intermediaries spend to process OPO/HL cost reports) | $ 12,951 |

13. Capital Costs

There are no capital costs.

14. Federal Cost

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| (1) | Printing initial distribution 1,000 copies of Form CMS 216-94 | $ 300 |
| (2) | Printing initial distribution of 225 copies of instruction Manual. The instructions to this form will be issued as a part of the Provider Reimbursement Manual. | 170 |

Accordingly, the instructions will not be reprinted each time the form is reprinted.

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| (3) | Total cost of printing | $ 470 |

15. Program Changes

There have been no changes.

16. Publication and Tabulation Dates

There are no publication plans for the data.

17. Expiration Date

There are no objections to displaying the expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

This collection of information does not employ statistical methods.